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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,493

09/16/2003

Joseph P. Errico

F-289

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09/15/2009

SPINE MP

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WESTFIELD, NJ 07090

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

09/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,493	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/29/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/09 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the angled distal surface of the tool being engageable in a plurality of ways must be shown or the feature(s) canceled from the claim(s). According to the claimed embodiment, there is only one way for the tool to engage the baseplates. It is understood that the claimed embodiment is Figs. 71-82. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15,18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation that the tool can be positioned in a plurality of ways or on any surface of the baseplate angled surfaces is not supported by the disclosure. The angled perimeter that engages a baseplate and also an angled spacer with angled upper and lower surfaces is only disclosed to engage the

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baseplates in one orientation. Note to Applicant if the other embodiments support this claim limitation, then the Examiner would like an explanation of how the claims are generic. It is the Examiner's position that they have been amended to a specific specie and these claims are not supported by the specie since claims 1 and 22 are not generic. As mentioned above, in the drawing objection, the Figs. 71-82 showing the claimed embodiment do not support multiple positioning. Correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (6117637) in view of McGahan et al. (WO 01/62191) and Jackson (6821298). Gill et al. disclose (Fig. 1a) an intervertebral spacer device **20** having a first baseplate **22** and a second baseplate **24**, with each including upper and lower surfaces, and a perimeter. It can be seen that the first and second baseplates are mounted to one another such that they can articulate relative to one another. Gill also discloses (Fig. 14a) a manipulation tool **70** having a correspondingly distal surface **76** that when engaged with the perimeter of the baseplates, rotation of the baseplates relative to the corresponding distal surface of the manipulation tool is prevented by interference between the perimeter of the baseplates and the corresponding distal surface of the manipulation tool. It can also be seen the manipulation tool further includes a spacer **84** protruding outwardly from the distal surface of the tool and has an upper surface and a

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lower surface. It is noted that Gill et al. show (Figs. 6,14b) the baseplates and tool have corresponding surfaces that appear angled, but do not explicitly state the contour of these surfaces. McGahan et al. illustrates (Fig. 15b) a spinal orthopedic set with a spinal implant **10** with angled perimeter surfaces having a central flat surface **22** flanked by two flat corner perimeter surfaces **18**, **26** that correspond to the angled distal end of the tool having central surface **128** and two flanked flat surfaces **126**, **130** to engage the implant. McGahan teaches that angled perimeter flat surfaces are provided to prevent rotation of the implant when inserting with the tool, page 12, lines 21-24. McGahan also shows (Fig. 22B) a difference in dimension of the implant surface and the tool engaging surface. McGahan show (Figs. 29A,B) another insertion tool and implant where the corresponding angled surfaces comprise a central flat surface flanked by two adjacent flat surfaces and thus form corners. However, Gill et al. also fail to disclose the spacer having angled upper and lower surfaces. Jackson teaches (Fig. 9) a spinal device that has a spacer **103** having upper and lower angled surfaces **133**, clearly seen in Fig. 12. It would have been obvious to one of ordinary skill in the art to use angled perimeters that correspond for a tool and spinal plate structure as taught by McGahan et al. with the implant and tool of Gill et al. and also use angled upper and lower surfaces for the spacer as taught by Jackson with the spacer portions of Gill et al. such that by using the modified angled surfaces that match or correspond when engaged together do not allow for movement. Such a modification only involves routine skill in the art and would have predictable results. Any non-angled surfaces, i.e. curvate have the risk of sliding and would not be desirable when a surgeon is inserting the implant into the patient's

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vertebral space and thus the modification of using angled surfaces by the teachings of McGahan and Jackson provide an obvious expedient to thus provide the first baseplate to be lordodically angled with respect to the second baseplate as the lower surface of the first baseplate is held against the upper angled surface of the spacer in a nonmovable engagement. With respect to claims 13-15,18-20 as best understood, if Applicant means that the apparatus can be oriented in a plurality of ways based on how the surgeon desires accessing the spinal space, then the baseplates and tool of Gill as modified with McGahan and Jackson are fully capable of being positioned in a plurality of ways based on the decision of the surgeon.

Response to Arguments

Applicant's arguments with respect to claims 1,22 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738